

### **REMARKS/ARGUMENTS**

This is in response to the Office Action mailed October 4, 2005.

Claims 1, 22, and 24 have been amended, claims 4 and 25 have been cancelled, and new claims 28-31 have been added. Support for amendments to claims 1, 22 and 25 can be found throughout the originally filed application, e.g., original claims 4 and 25 and paragraphs 47 and 51. Support for new claims 28-31 can be found throughout the originally filed application, e.g., table 4. No new matter is introduced and these are not intended to be narrowing amendments. Independent claim 1 and its dependent claims 2-21 and 28-30, independent claim 22 and its dependent claims 23 and 31, and independent claim 24 and its dependent claims 25-27 are currently pending and at issue.

#### **Claim Rejections - 35 U.S.C. §101**

Claims 1-3 and 5-24 have been rejected under 35 U.S. C. §101, as being directed to non-statutory subject matter. The Examiner asserts that first, for a process claims to pass muster, the recited process must somehow apply, involve, use or advance the technological arts and that the instant invention fails to recite the use of any type of technology within the recited steps of communicating the benefit of consuming calcium-containing products. The Examiner further argues that second, although the claimed invention produces a useful, concrete and tangible result, since the claimed invention as a whole is not within the technological arts, the claims are deemed to be directed to non-statutory subject matter.

The Applicants disagree with the Examiner that the claims do not apply, involve, use and advance technological arts. The present claims involve the technological arts in the use of

calcium or dairy to regulate of body weight, a premise of which is well established and supported throughout the originally filed application, e.g., Examples 1 and 2.

In order to facilitate prosecution, the Applicants have amended the independent claims to include features from original claims 4 and 25. The Examiner had not objected to claims 4 and 25 under §101, so the claims as amended should not be rejected under §101. The Applicants respectfully request that this rejection be withdrawn.

### **Claim Rejections - 35 U.S.C. §103**

Claims 1-20 and 22-27 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Mazer (US 5,698,222) in view of Hinz (US 6,403,657) and further in view of Tannehill (US 5,158,310).

In regards to independent claims 1, 22 and 24, the Examiner asserts that the combination of Mazer and Tannehill teaches a method of communicating to a consumer that consuming calcium-containing products have a beneficial effect, the communicating being by an entity having a commercial interest in the consumption of the product. The Examiner admits that Mazer fails to teach that said beneficial effect is on body weight or body fat, but asserts that Hinz allegedly teaches a method of using calcium supplements to combat obesity, and that the combination of these three references renders the present claims obvious.

The Examiner has not established a *prima facie* case of obviousness as set forth in MPEP 706.02(j), because one skilled in the art would not be motivated to combine the cited references. Mazer and Hinz teach away from the present claims and Tannehill has nothing to do with calcium, dairy or weight or fat management, as discussed below. Moreover, even if the references can be combined, the references do not teach or expressly or impliedly suggest all the

claim limitations. In addition, due to the present invention's unexpected results, there has been a significant shift in the scientific community and the food industry, which has supported and endorsed the methods of the present invention leading to significant recognition and commercial success.

Applicants contend that the present invention is distinct from all three references because none of the cited or applied references, either alone or in combination, disclose, teach or suggest the methods of independent claims 1, 22, and 24.

Mazer is directed to a solid calcium supplement which is mainly fortified calcium glycerophosphate (CaGP) and vitamin D<sub>3</sub> (column 1, lines 5-7). At most, Mazer teaches that calcium is an essential nutrient that is a major component of mineralized tissues and is required for normal growth and development of the skeleton and teeth, and may be used to prevent osteoporosis (column 1, lines 10-15). As the Examiner concedes, Mazer "fails to teach the communicating being by an entity having a commercial interest in the consumption of the product." Also, nowhere in Mazer is calcium or dairy taught to effect or benefit body weight, body fat, weight or obesity control.

Moreover, Mazer selects CaGP for its solubility profile, taste and stability at lower pH (column 24, lines 4-52). In fact, Mazer teaches in the "background of the invention" section that "[d]airy products are the major contributors of dietary calcium because of their high calcium content... and frequency of consumption... [h]owever, many persons, especially women, prefer to limit their intake of dairy products for several reasons... they perceive that some dairy products are too high in fat or protein and may lead to weight gain." (Column 2, lines 39-50). Mazer's teaching that their product must contain only CaGP as the calcium salt and vitamin D<sub>3</sub>,

and not dairy because of its perception that dairy may lead to weight gain teaches away from methods of communicating the benefits of calcium products such as dairy products to benefit weight loss. There would be no reason to combine this reference with the others.

Hinz teaches a pharmacological therapy using Phentermine and/or Diethylpropion with an SSRI medication, Citalopram, to effectuate weight loss, appetite suppression and treatment of obesity, in conjunction with replacement of vitamins to counter nutritional deficiency (column 4, line 59-column 5, line 2). Calcium is mentioned only to assist in avoiding nutritional deficiency (column 4, lines 23-25), e.g., using 50 mg to 2,000 mg per day to prevent bone demineralization (column 5, line 67- column 6, line 2).

To the contrary, the present invention is directed to methods of communicating the benefits of dairy or other calcium-containing products on body weight, body fat, weight-control or obesity-control. Hinz does not teach, disclose or suggest such a method, explicitly or inherently. Hinz's reliance on active pharmacologic agents teaches away from communicating benefits of calcium or dairy itself as a weight, fat or obesity control agent.

Tannehill is directed to a display system which includes a visual display unit mounted on a shopping cart (abstract). The display is used as advertising but nowhere in Tannehill is calcium or weight control mentioned, or communications relating to the benefits of consuming them.

Applicants contend that there was no motivation to combine the teaching of Mazer, Hinz or Tannehill. Mazer relates to a specific product, calcium glycerophosphate, for which there would be no motivation to combine with a pharmaceutical product such as Hinz, or a shopping cart display, such as Tannehill. Hinz relates to pharmaceuticals with mineral calcium and there would be no motivation to combine such a reference with Mazer which relates to an organic

calcium material. Also, limitations on advertising pharmaceuticals would make a display system such as Tannehill's inappropriate.

Prior to the invention recited here, there was no recognition that calcium or dairy in food products or the diet would be beneficially or therapeutically effective to promote weight loss, and therefore, it could not have been obvious to communicate such benefits. The importance of maintaining high calcium intake and dairy during attempts to lose, maintain or control weight was previously unrecognized and was unexpected prior to Dr. Zemel's pioneering work.

Due to these unexpected results, there has been a significant shift in the scientific community and the food industry, which has supported and endorsed the communication methods of the present invention. The inventive methods have achieved considerable public recognition and commercial success, as indicated by the attached documentation.

Page one of the attached material lists various clinical trials conducted by Dr. Zemel further showing the beneficial effects of consuming high calcium and dairy in accelerating the effects of weight loss in humans. Page two shows how the food industry has adopted the novel communication methods of the present invention. For example, the label "3-A-Day Milk Cheese Yogurt, Burn more fat, lose weight" communicates the message that increasing dairy consumption to at least three servings a day supports weight loss. As set forth on page two, over 50 top U.S. retail chains have licensed the inventive methods and are promoting the inventive methods by placing labels with the weight loss message on over 2.5 billion dairy packages to date. Pages three, four and five evidence various examples of leading industry packages and consumer advertisements. Page six provides testimonials about the inventive methods from notable health professional associations. The American Academy of Family Physicians refers to "dairy nutrition

and its contribution to weight management." The National Medical Association recognizes that "[s]ome of the information that was presented today shows a clear beneficial relationship between the daily intake of three to four servings of dairy products and the reduction of obesity." The American Dietetic Association praises Dr. Zemel's work in that "[i]t has been exciting to see how emerging research on the role of calcium and dairy products adds to the body of knowledge about preventing and treating obesity [and t]his information provides additional tools for dietetics professionals to use in their day-to-day practice."

Applicants further contend that even with widespread recognition, the claimed method is so unexpected that there remains skepticism about communicating the effects of calcium/dairy on weight loss. For example, there have been advertisements asserting that Yoplait yogurt promotes weight loss (advertising claims that are subject to a license agreement under the present patent application). A challenge was filed by an anonymous party, who argued that there was no support for the claim that calcium consumption promotes weight loss. The challenger apparently doubted the efficacy of the invention as claimed in the present application. The National Advertising Division (NAD) of the U.S. Better Business Bureau ruled that the evidence (research by Dr. Zemel) supported General Mills' advertisement of the weight loss benefits of the calcium-containing dairy product (decision attached). This dispute, and its conclusion accepting the surprising evidence of the weight loss efficacy of calcium, further evidences the non-obviousness of the claimed invention. See also Express Article, published by Express Publications, a subsidiary of the Washington Post Company, 7/19/05, p. 10 (provided in concurrently filed IDS).

Therefore, neither Hinz, Mazer nor Tannehill, alone or in combination, disclose, teach or suggest the claim invention as set forth in claims 1, 22, or 24, or dependant claims 2-21, 23, 25-

29 and 31. The dependant claims include additional limitations distinguishing them from the cited references. For example, claims 23 and 28-31 recite communicating regarding the benefits of specific amounts of calcium.

The Examiner also rejected claim 21 under 35 U.S.C. §103(a) as being unpatentable over Mazer, in view of Hinz and further in view of Christiansen (6,159,530). Christiansen refers in example 4 to a cereal containing a particular brand of calcium chelate, but does not describe communicating a trademark for a calcium-containing product for the purposes recited in the present claims. Christiansen does not disclose, teach, suggest and/or cure the defects of Hinz and Mazer as discussed above with respect to claim 21.

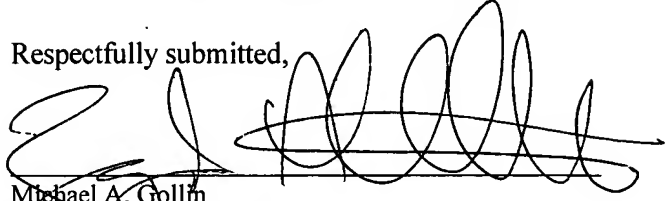
Therefore, claims 1-31 are patentable because none of the cited references, either alone or in combination, disclose, teach or suggest the present invention.

#### **Conclusion**

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. Accordingly, Applicants request that the Examiner issue a Notice of Allowance indicating the allowability of claims 1-31 and that the application be passed to issue. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is hereby invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment is respectfully requested.

Respectfully submitted,

A large, stylized handwritten signature in black ink, consisting of several loops and a long horizontal stroke.

Date: March 6, 2006

Michael A. Gollin

Registration No. 31,957

Zayd Alathari

Registration No. 42,256

VENABLE

P.O. Box 34385

Washington, D.C. 20043-9998

Telephone: (202) 962-4800

Telefax : (202) 962-8300

Dc2/688990